

PATENT  
Docket No. 300622004620

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

Express Mail Label No. E1 796955920 US

Date of Deposit: March 4, 2002

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

*Vicki Andrews*  
Vicki Andrews

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In the application of:

Rajesh S. GOKHALE et al.

Serial No.: To Be Assigned

Filing Date: Herewith

For: METHODS TO MEDIATE  
POLYKETIDE SYNTHASE MODULE  
EFFECTIVENESS

Examiner: To Be Assigned

Group Art Unit: To Be Assigned

J1046 U.S. PTO  
10/091244  
03/04/02

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial Number 09/500,747, filed February 9, 2000, and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R. § 1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the application.

This application claims the benefit of the filing date of provisional application serial number 60 119,363, filed February 9, 1999.

This Information Disclosure Statement is submitted:

- ☒ With the application; accordingly, no fee or separate requirements are required.
- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \* is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of \* is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 300622004620. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 4, 2002

Respectfully submitted,

By: Brenda J. Wallach  
Brenda J. Wallach  
Registration No. 45,193

Morrison & Foerster LLP  
3811 Valley Centre Drive  
Suite 500  
San Diego, California 92130-2332  
Telephone: (858) 720-7961  
Facsimile: (858) 720-5125

Form PTO-1449 <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> <i>(Use several sheets if necessary)</i>	Docket Number 300622004620	Application Number To Be Assigned
	Applicant Rakesh S. GOKHALE et al	
	Filing Date Herewith	Group Art Unit To Be Assigned
	Mailing Date March 1, 2002	

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	11/1985	4,551,433	DeBoer	435	253	
	2.	10/1989	4,874,748	Katz <i>et al.</i>	514	29	
	3.	06/1990	4,935,340	Baltz <i>et al.</i>			
	4.	11/1991	5,063,155	Cox <i>et al.</i>	435	76	
	5.	03/1992	5,098,837	Beckmann <i>et al.</i>	435	172.3	
	6.	09/1992	5,149,639	Katz <i>et al.</i>	435	76	
	7.	12/1992	5,168,052	Cox <i>et al.</i>	435	72	
	8.	10/1993	5,252,474	Gewain <i>et al.</i>	435	172.3	
	9.	12/1995	5,475,099	Knauf <i>et al.</i>			
	10.	05/1996	5,514,544	Rao <i>et al.</i>	435	6	
	11.	09/1997	5,672,491	Khosla <i>et al.</i>	435	148	
	12.	01/1998	5,712,146	Khosla <i>et al.</i>	435	252.35	
	13.	10/1998	5,824,513	Katz	435	76	
	14.	11/1998	5,830,750	Khosla <i>et al.</i>	435	252.35	
	15.	12/1998	5,843,718	Khosla <i>et al.</i>	435	69.1	
	16.	12/1999	6,004,787	Katz <i>et al.</i>	435	183	
	17.	05/2000	6,060,234	Katz <i>et al.</i>	435	4	
	18.	06/2000	6,063,561	Katz <i>et al.</i>	435	4	
	19.	05/2000	6,066,721	Khosla <i>et al.</i>			
	20.	06/2000	6,080,555	Khosla <i>et al.</i>			
	21.	03/2001	6,200,813	Katz <i>et al.</i>	435	477	
	22.	08/2001	6,271,255	Leadlay <i>et al.</i>	514	450	

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
-------------------	----------	------	--------------	---------	-------	----------	--------------------

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary.)</i>	Docket Number 300622004620	Application Number To Be Assigned
	Applicant  Rajesh S. GOKHALE et al	
	Filing Date Herewith	Group Art Unit To Be Assigned
	Mailing Date March 1, 2002	

	23.	07/1993	WO 93/13663	WIPO				
	24.	03/1995	WO 95/08548	WIPO				
	25.	12/1996	WO 96/40968	WIPO				
	26.	01/1997	WO 97/02358	WIPO				
	27.	04/1997	WO 97/14789	WIPO				
	28.	01/1998	WO 98/01546	WIPO				
	29.	01/1998	WO 98/01571	WIPO				
	30.	06/1998	WO 98/27203	WIPO				
	31.	11/1998	WO 98/49315	WIPO				
	32.	12/1998	WO 98/54308	WIPO				
	33.	01/2000	WO 00/01838	WIPO				

**OTHER DOCUMENTS***(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	34.	Aparicio et al., J. of Biol. Chem. (1994) 269(11):8524-8528
	35.	Aparicio, <i>Gene</i> (1996) 169:9-16
	36.	Bao, W. et al. (1998). <i>Biochemistry</i> 37(22):8132-8138
	37.	Bartel et al., J. Bacteriol. (1990) 172(9):4816-4826
	38.	Beck et al., Eur. J. Biochem. (1990) 192:487-498
	39.	Bedford, D. et al. (1996). <i>Chem &amp; Biol</i> 3(10):827-831
	40.	Bevitt et al., Eur. J. Biochem. (1992) 204:39-49
	41.	Bibb et al., EMBO J. (1989) 8(9):2727-2736
	42.	Bohm et al., <i>Chem. &amp; Biol.</i> (1998) 5:407
	43.	Brown et al., J. Chem. Soc. Chem. Commun. (1995) 15:1517-1518
	44.	Caballero et al., Mol. Gen. Genet. (1991) 230:401-412
	45.	Caffrey et al., Eur. J. Biochem. (1991) 195:823-830
	46.	Caffrey et al., FEBS Lett. (1992) 304:225-228
	47.	Cane et al., J. Am. Chem. Soc. (1993) 115:522-526
	48.	Cane et al., J. Antibiotics (1995) 48:647-651
	49.	Corcoran et al., in 5th International Congress of Chemotherapy, Vienna, Abstracts of

EXAMINER:

DATE CONSIDERED:

EXAMINER Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>	Docket Number 300622004620	Application Number To Be Assigned
	Applicant  Rajesh S. GOKHALE et al.	
	Filing Date Herewith	Group Art Unit To Be Assigned
	Mailing Date March 1, 2002	

	Communications (1967) pp. 35-40
50	Corcoran, ed., in Antibiotics Volume IV Biosynthesis, Springer-Verlag, New York (1982) pp. 145-150
51	Cortes et al., Nature (1990) 348:176-178
52	Dalbie-McFarland et al., Proc. Natl. Acad. Sci. USA (1982) 79:6409
53	Davis et al., Abst. of the Genetics of Industrial Microorganisms Mtg. (1994) P288:192
54	Dimroth et al., Eur. J. Biochem. (1970) 13:98-110
55	Donadio et al., Gene (1992) 111:51-60
56	Donadio et al., Gene (1992) 115:97-103
57	Donadio et al., Industrial Microorganism, Basic and Applied Molecular Genetics, R. H. Baltz, G.D. Hegeman and P.L. Skatrud (eds) (Amer. Soc. Microbial.), Washington, D.C. (1993) pp. 251-265
58	Donadio et al., Proc. Natl. Acad. Sci. USA (1993) 90:7119-7123
59	Donadio et al., Science (1991) 252:675-679
60	Evans et al., J. Am. Chem. Soc. (1992) 114:9434-9453
61	Fernandez-Moreno et al., Cell (1991) 66:769-780
62	Fernandez-Moreno et al., J. Biol. Chem. (1992) 267:19278-19290
63	Floss, Tetrahedron (1991) 47(31):6045-6058
64	Fu et al., "Engineered Biosynthesis of Novel Polyketides: Stereochemical Course of Two Reactions Catalyzed by a Polyketide Synthase," <i>Biochemistry</i> (1994) 33:9321-9326
65	Geisselsoder et al., BioTechniques (1987) 5:786
66	Gokhale et al., <i>Biochemistry</i> (1998) 37:2524-2528
67	Gokhale et al., <i>Science</i> (1999) 284:482-485
68	Gordon et al., Acc. Chem. Res. (1996) 29(3):144-154
69	Hallam, Gene (1988) 74:305-320
70	Hamilton et al., J. Bacteriol. (1989) 171:4617
71	Hershberger et al. (1989) "Genetics and Molecular Biology of Industrial Microorganisms," Am. Soc. for Microbiol. (Washington, DC) pp. 68-84
72	Hopwood et al., Nature (1985) 314(6012):642-644
73	Hopwood et al., Phil. Trans. R. Soc. Lond. B (1989) 324:549-562
74	Hopwood et al., Secondary Metabolites: Their Function and Evolution (1992) Wiley Chichester (Ciba Foundation Symposium 171) pp. 88-112
75	Hunaitit et al., Antimicrobial Agents and Chemotherapy (1984) 25(2):173-178

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	

Form PTO-1449  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>	Docket Number 300622004620	Application Number To Be Assigned
	Applicant  Rajesh S. GOKHALE et al	
	Filing Date Herewith	Group Art Unit To Be Assigned
	Mailing Date March 1, 2002	

76.	Hutchinson, Bio Technology (1994) 12:375-380
77.	Ireland et al., J. Org. Chem. (1980) 45:1868-1880
78.	Jay et al., J. Biol. Chem. (1984) 259:6311-6317
79.	Kakavas, S. et al. (1997), <i>J of Bacteriology</i> 179(23):7515-7522
80.	Kao et al., J. Am. Chem. Soc. (1994) 16:11612-11613
81.	Kao et al., J. Am. Chem. Soc. (1995) 117(35):9105-9106
82.	Kao et al., J. Am. Chem. Soc. (1996) 118(38):9184-9185
83.	Kao et al., J. Am. Chem. Soc. (1997) 119(46) 11339-11340
84.	Kao <i>et al.</i> , "Engineered Biosynthesis of a Complete Macrolactone in a Heterologous Host," <i>Science</i> (1994) 265:509-512
85.	Kao et al., Biochemistry (1996) 35:12363-12368
86.	Katz et al., Ann. Review Microbiol. (1993) 47:875-912
87.	Khosla et al., J. Bacteriol. (1993) 175:2197-2204
88.	Khosla et al., Molec. Microbiol. (1992) 6(12):3237-3249
89.	Khosla, "Harnessing the Biosynthetic Potential of Modular Polyketide Synthases," <i>Chem Rev</i> (1997) 97:2577-2590
90.	Khosla <i>et al.</i> , "Generation of Polyketide Libraries Via Combinatorial Biosynthesis," <i>Trends Biotechnol</i> (1996) 14(9):335-341
91.	Kramer et al., J. Am. Chem. Soc. (1997) 119(4):635-639
92.	Kuhstoss et al., Gene (1996) 183:231-236
93.	Kunkel, Proc. Natl. Acad. Sci. USA (1985) 82:448
94.	Lambalot et al., J. Antibiotics (1992) 45:1981-1982
95.	Lanz et al., J. of Biol. Chem. (1991) 266(15):9971-9976
96.	Lau et al., Biochemistry (1999) 38:1643-1651
97.	Leadlay et al., Biochem. Soc. Transactions (1993) 21:218-222
98.	Lehrer et al., J. Immun. Meth. (1991) 137:167-173
99.	MacNeil, J. Bacteriol. (1988) 170:5607
100.	MacNeil et al., Gene (1992) 115:119-125
101.	Malpartida et al., Nature (1984) 309:462-464
102.	Malpartida et al., Mol. Gen. Genet. (1986) 205:66-73
103.	Malpartida et al., Nature (1987) 325(6107):818-821

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	

Form PTO-1449  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>	Docket Number 300622004620	Application Number To Be Assigned
	Applicant  Rajesh S. GOKHALE et al.	
	Filing Date Herewith	Group Art Unit To Be Assigned
	Mailing Date March 1, 2002	

104.	Marsden et al., Science (1994) 263:378-380
105.	Marsden et al., Science (1998) 279:199-202
106.	Martin et al., J. Am. Chem. Soc. (1997) 119:3193
107.	Masamune et al., J. Am. Chem. Soc. (1975) 97:3512-3513
108.	Masumoto et al., Tetrahedron Lett. (1988) 29:3575
109.	McAlpine et al., The Journal of Antibiotics (1987) 40(8):1115-1122
110.	McDaniel, R. et al. (1997). Chem & Biol 4(9):667-674
111.	McDaniel et al., "Engineered Biosynthesis of Novel Polyketides," Science (1993) 262:1546-1550
112.	Oliynyk et al., Chem. and Biol. (1996) 3:833-839
113.	Omura et al., J. Biochem. (1974) 75:193-195
114.	Perun, Drug Action and Drug Resistance in Bacteria, Vol. 1, S. Mitsuhashi (ed.) Univ. Park Press, Baltimore, 1977
115.	Pieper et al., Biochemistry (1997) 36:1846-1851
116.	Ranganathan et al., "Knowledge-based Design of Bimodular and Trimodular Polyketide Synthases Based on Domain and Module Swaps: A Route to Simple Statin Analogues," Chem & Biol (1999) 6:731-741
117.	Roberts et al., FEBS Lett. (1983) 159(1,2):13-16
118.	Roberts et al., Biochem. Soc. Transactions (1984) 12 642-643
119.	Roberts et al., Biochem. Soc. Transactions (1992) 21 325
120.	Roberts et al., Eur. J. Biochem. (1993) 214:305-311
121.	Robinson, Phil. Trans. R. Soc. Lond. B (1991) 332:107-114
122.	Rohr, "Combinatorial Biosynthesis - An Approach in the Near Future?," Angew Chem Int Ed Engl (1995) 34(8):881-888
123.	Ruan et al., J. of Bacteriology (1997) 79(20):6416-6425
124.	Rudd et al., J. Gen. Microbiol. (1979) 114:35-43
125.	Sanz et al., Eur. J. Biochem. (1996) 235:601-605
126.	Shen et al., Science (1993) 262:1535-1540
127.	Sherman et al., J. Bacteriol. (1992) 174:6184-6190
128.	Sherman et al., EMBO J. (1989) 8:2717-2725
129.	Spencer et al., Biochem. J. (1992) 288:839-846
130.	Staunton et al., Nat. Struct. Biol. (1996) 3:188-192
131.	Staunton et al., "Biosynthesis of Erythromycin and Rapamycin," Chem Rev (1997) 97:2611-2629

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	



Form PTO-1449  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>	Docket Number 300622004620	Application Number To Be Assigned
	Applicant  Rajesh S. GOKHALE et al	
	Filing Date Herewith	Group Art Unit To Be Assigned
	Mailing Date March 1, 2002	

132.	Strohl et al., Molecular Microbiology (1992) 6(2):147-152
133.	Strohl et al., Society of Industrial Microbiology (1991) 7:163-174
134.	Tang et al., Chem. Biol. (2000) 7:77-84
135.	Toshima et al., J. Am. Chem. Soc. (1995) 117:3717
136.	Tsai et al., Chemistry & Biology (1985) 2:355-362
137.	Tuan et al., Gene (1990) 90:21
138.	Vedejs et al., J. Am. Chem. Soc. (1987) 109:5437-5446
139.	Vedejs et al., J. Am. Chem. Soc. (1989) 111:8430-8438
140.	Wawszkiewicz et al., Biochemische Zeitschrift (1964) 340:213-227
141.	Wiseman et al., Chemistry & Biology (1995) 2(9):583-589

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	